

# Step Therapy/Prior Authorization Criteria for HMG-CoA Reductase Inhibitors (Statins), Niacin, Ezetimibe and Combinations

#### **Background**

The Antilipidemic-1 drug class includes several statins [lovastatin (Mevacor, Altoprev), simvastatin (Zocor), pravastatin (Pravachol), fluvastatin (Lescol, Lescol XL), atorvastatin (Lipitor), rosuvastatin (Crestor), and pitavastatin (Livalo)], niacin (Niaspan), ezetimibe (Zetia), and combinations of statins with ezetimibe (Vytorin), niacin (Simcor, Advicor) or antihypertensives (Caduet). Currently, Livalo is the only non-formulary agent Antilipidemic-1 class. Vytorin, Crestor, Caduet, Lescol, Lescol XL, Simcor, Advicor, Altoprev and Livalo are subject to prior authorization.

DoD's preferred agents for patients who require therapy with one of the agents from the Antilipidemic-1 are the generics (lovastatin, simvastatin, pravastatin,), and the branded agent Lipitor.

In order to promote use of preferred agents for those patients who require drugs in the Antilipidemic-1 class, step therapy/prior authorization requirements apply to Vytorin, Crestor, Caduet, Lescol, Lescol XL, Simcor, Advicor, Altoprev and Livalo. TRICARE coverage for these agents depends on whether you meet step therapy/prior authorization criteria.

#### What is Step Therapy?

Step therapy involves prescribing a safe, cost effective medication as the first step in treating a medical condition. The preferred medication is often a generic medication that offers the best overall value in terms of safety, effectiveness, and cost. Non-preferred (second-step) drugs are only prescribed if the preferred medication is ineffective or poorly tolerated.

Vytorin, Crestor, Caduet, Lescol XL, Simcor, Advicor, Altoprev and Livalo will only be approved for first time users after they have tried one of the preferred agents that provides similar LDL-lowering capability. Beneficiaries who filled a prescription for one of the restricted drugs during the last 180 days will not be affected by step therapy requirements and won't have to switch medications.

#### Patients receiving Lipitor, Lovastatin, Simvastatin, or Pravastatin

You will be able to continue to receive Lipitor at the same \$9 cost share. Generic lovastatin, simvastatin, and pravastatin are available at a \$3 generic cost share.

### Patients currently receiving Vytorin, Crestor, Caduet, Lescol, Lescol XL, Simcor, Advicor, or Altoprev

If you have filled a prescription for Vytorin, Crestor, Caduet, Lescol, Lescol XL, Simcor, Advicor, or Altoprev through your TRICARE benefit during the previous 180 days, you will be able to continue to receive these medications at a \$9 (Tier 2) cost share.

Cost shares for patients currently receiving Vytorin, Crestor, Caduet, Lescol, Lescol XL, or Altoprev

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	Retail network pharmacy (up to a 30-day supply)	Mail order pharmacy (up to a 90-day supply)	Military Treatment Facility
Generic lovastatin, simvastatin, or pravastatin	\$3	\$3	\$0
Lipitor, Vytorin, Crestor, Caduet, Lescol, Lescol XL, Simcor, Advicor, or Altoprev	\$9	\$9	\$0

### Patients starting treatment with Vytorin, Crestor, Caduet, Lescol, Lescol XL, Simcor, Advicor, Altoprev or Livalo

You must have tried generic lovastatin, simvastatin, pravastatin or Lipitor in the previous 180 days in order for TRICARE to cover a prescription for these agents, unless you meet prior authorization criteria.

## Cost shares for patients starting treatment with Vytorin, Crestor, Caduet, Lescol, Lescol XL, Simcor, Advicor, Altoprev or Livalo

	Retail network pharmacy (up to a 30-day supply)	Mail order pharmacy (up to a 90-day supply)	Military Treatment Facility
Generic lovastatin, simvastatin, or pravastatin	\$3	\$3	\$0
Lipitor	\$9	\$9	\$0
Vytorin, Crestor, Caduet, Lescol, Lescol XL, Simcor, Advicor, Altoprev	Must try Lipitor, generic lovastatin, simvastatin, or pravastatin in strengths providing similar LDL lowering capability <sup>1</sup>		
Livalo*	Must try Lipitor, generic lovastatin, simvastatin, or pravastatin in strengths providing similar LDL lowering capability <sup>1</sup>		
Or meet prior authorization		roviding similar LDL lowering ca	apability <sup>1</sup>

<sup>\*</sup>Non-formulary cost shares apply to Livalo: Retail network pharmacy \$22 (Up to a 30 day supply); Mail order pharmacy \$22 (up to a 90 day supply). Cost share may be reduced to the formulary cost share if medical necessity is established.

#### **Prior Authorization Criteria**

The following criteria were established by the DoD P&T Committee at their May 2010 meeting. The prior authorization form for these medications is available on the <a href="IRICARE Pharmacy Prior Authorization page">IRICARE Pharmacy Prior Authorization page</a>. The effective date is 6 October 2010.

## Step Therapy / Prior Authorization Criteria

TRICARE will NOT cover second-step agents for new patients—defined as patients who have not filled at least one prescription for a first-step drug (generic lovastatin, simvastatin, pravastatin or Lipitor in dosages that provide similar LDL lowering) in the previous 180 days at any DoD Pharmacy point of service— UNLESS the patient meets one of the following criteria:

- 1. The patient requires greater than 55% LDL lowering.
- 2. The patient has tried a first-step medication with similar LDL reduction and was unable to tolerate it due to adverse effects.
- 3. The patient is taking a concurrent drug that is metabolized by CYP3A4.
- 4. The patient requires primary prevention with Crestor and is not able to take Lipitor (atorvastatin).
- 5. The patient requires a drug that lowers LDL and raises HDL AND cannot take two separate tablets.

Criteria approved through the Uniform Formulary decision-making process (13 May 2010).

First-Step Medications and Dosages Required to Obtain Second-Step Medications

Second-Step Medications	First-Step Medications: Automated Step Therapy criteria requires new users to try a First-Step	
	medication with a similar targeted LDL reduction before obtaining a Second-Step medication	
Altoprev10mg Lescol20mg	Any strength of Lovastatin OR Pravastatin OR Simvastatin OR Lipitor	
Altoprev20mg	Lovastatin>20mg OR	
Lescol40mg	Pravastatin>20mg OR	
Livalo 1mg	Simvastatin>10mg OR	
Advicor 20mg	Lipitor ≥10mg	
Altoprev40mg	Lovastatin>40mg OR	
LescolXL 80mg	Pravastatin>40mg OR	
Caduet 10mg	Simvastatin>20mg OR	
Livalo 2mg	Lipitor ≥10mg	
Simcor 20mg		
Advicor 40mg		
Crestor 5mg	Pravastatin80mg OR	
Vytorin10/10mg	Simvastatin <u>&gt;</u> 40mg OR	
Altoprev 60mg	Lipitor >20mg	
Caduet 20mg		
Livalo 4mg		
Crestor >10mg	Lipitor >40mg (preferred)	
Vytorin ≥10/20mg	OR	
Caduet <u>&gt;</u> 40mg	Simvastatin 80mg	

A new user is defined as a patient who has been prescribed a second-step medication and does not have a prescription for the second-step medication in their profile during the last 180 days.

Existing users are able to continue to obtain any strength of the Second-Step medication that is present on PDTS profile.

If a patient does not meet automated Step Therapy criteria, then the manual Prior Authorization process and criteria are applicable.

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